

Puerto Rico Department of Health Intends to Repeal Regulation No. 120

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An McV Health Care Alert

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The Puerto Rico Department of Health recently issued a public notice of its intent to repeal the Secretary of Health's Regulation No. 120 to Regulate the Establishment and Operation of Clinical Analysis Laboratories, Anatomic Pathology Laboratories, and Blood Banks in Puerto Rico of August 4, 2006, as amended ("Regulation No. 120").

Regulation No. 120 would be replaced by a proposed regulation (the "Proposed Regulation") to be adopted by the Puerto Rico Department of Health, a copy of which is available at the Puerto Rico Department of Health website.

The Proposed Regulation is intended to bring the Department of Health's regulations in line with the statutory and regulatory provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Among other matters, the Proposed Regulation would (i) authorize phlebotomists to take blood samples for clinical analysis; (ii) allow nursing staff in dialysis centers to perform certain waived tests, provided they have obtained a CLIA Certificate of Waiver; and (iii) increase the price of license applications. The Proposed Regulation also includes provisions to regulate the establishment and operation of plasmapheresis centers.

The general public has until November 18, 2022 to submit comments to the Puerto Rico Department of Health, by mail at P.O. Box 70184, San Juan, P.R. 00936-8184, or by email at a.ruiz@salud.pr.gov and nilda.ortiz@salud.pr.gov.

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